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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No.:

09/234,532

Group Art Unit:

1623

Filing Date:

January 21, 1999

Applicant:

Sapse

Entitled:

COMPOSITION OF ANTI-HIV DRUGS AWND ANTI-

CORTISOL COMPOUNDS AND METHOD FOR DECREASING

THE SIDE EFFECTS OF ANTI-HIV DRUGS IN A HUMAN

Assistant Commissioner for Patents

Washington, D.C. 20231

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8 (A)

Date of Deposit: January 28, 2000

I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as first-class mail in an envelope addressed to Assistant Commissioner for Patents, Washington, D.C. 20231

Jody K. Prince

Sir:

## INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §§ 1.97-1.98

As authorized and encouraged under 37 CFR §§ 1.97-1.98 and the provisions of MPEP §§ 609 and 707.05 (b), applicant submits herewith certain patent references, publications and/or other information which the Patent and Trademark Office may wish to consider in examining the above-identified patent application. The references and information are listed below and on attached form PTO-1449.

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- 6. Gatti, "Inhibition by Cortisol of Human Natural Killer (NK) Cell Activity," <u>J. Steroid Biochem</u>, 26, 1, 49-58 (1987).
- 7. Nestler, "Dehydroepiandrosterone Reduces Serum Low Density Lipoprotein Levels and Body Fat but Does not Alter Insulin Sensitivity in Normal Men," <u>J. Clin. Endocrinol.</u> Metab., 66, 1, 57-61 (1988)

A copy of each document is included for the express purpose of providing the Patent and Trademark Office with ample opportunity to evaluate the same and arrive at an independent assessment of the materiality of each, if any, to the examination of the above-identified application.

In reviewing the enclosed copies of the above documents, the Examiner is instructed to ignore any underscoring or highlighting which may have been done because such markings may or may not have any relationship to the subject matter of the above-identified application. The copies being submitted with this "Information Disclosure Statement" are the best copies available at this time.

The identification of any document herein is not intended to be, and should not be understood as being, an admission that each such document, in fact, constitutes "prior art" within the meaning of applicable law.

Applicants submit this statement in accordance with their duty of disclosure under 37 C.F.R. §1.56. This statement is filed in accordance with 37 C.F.R. 1.97(c), after the mailing date of a first Office Action on the merits, but before the mailing date of either a final action or a Notice of Allowance, and is accompanied by the following certification.

This disclosure statement is accompanied by a fee as required by 37 C.F.R. 1.97(c) in the amount of two-hundred and forty dollars (\$240.00) as set forth in 37 C.F.R. 1.17(p).

A copy of each reference, together with a listing on form PTO-1449, is submitted herewith. Applicants respectfully solicit the Examiner's consideration of the cited references and entry into the record of this application.

Applicant respectfully requests that the documents cited herein be made of record in the normal manner and that such documents appear on the printed patent as being considered and made of record.

Respectfully submitted,

Date: /-/0-00

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U.S. PATENT NEMBER	INVENTOR(S)	
5,804,571	Schein	
5,696,160	Miller	
5,360,613	Nissen	
5,348,979	Nissen, et al.	
5,283,258	Koch	
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5,028,440	Nissen	
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## FOREIGN PATENT DOCUMENTS

Country	Patent No.	Inventor(s)
EP	305,902	

## **OTHER DOCUMENTS**

- 1. Campbell, "Increased Steroidogenesis by Rat Zona GL Omerulosa Cells with Increased CE," J. of Clin. Endocrinology, 94, 2, 225-241 (1982)
- 2. Morales, "Effects of Replacement Dose of Dehydroepiandrosterone in Men and Women of Advancing Age," J. of Clin. Endocrinol. Metab., 78, 6, 1360-7 (1994)
- 3. Monteleone, "Effects of Phosphatidylserine on the Neuroendocrine Response to Physical Stress in Humans," Neuroendocrinology, 52, 3, 243-248 (1990)
- 4. Kerr, "Corticosteroid Modulation of Hippocampal Potentials: Increased Effect of Aging," Science, 245, 4925, 1505-1509 (1989)
- 5. Sapolsky, "Glucocorticoid-Sensitive Hipocamal Neurons Are Involved in Terminating the Adenocortical Stress Response," Proc. Natl. Acad. Sci. U.S.A., 81, 19, 6174-6177 (1984)